

K96 2823

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**Attachment VI: Summary of Safety and Effectiveness Information**

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Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer is compared to Synthes 2.7 mm Cannulated Screw and Threaded Washer.

Synthes 3.0 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 3.0 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot. The 3.0 mm Cannulated Screw and Threaded Washer are manufactured from 316L stainless steel or Ti-6Al-7Nb.

Synthes 2.7 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 2.7 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot. The 2.7 mm Cannulated Screw and Threaded Washer are manufactured from 316L stainless steel.

Synthes 3.0 mm Cannulated Screw and Threaded Washer are provided to the user sterile. Gamma Radiation will be used to sterilize the device.

In our opinion, Synthes 3.0 mm Cannulated Screw and Threaded Washer are at least equivalent to Synthes 2.7 mm Cannulated Screw and Threaded Washer, based on mechanical testing of both devices.